Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13546

0 - FRONT

11:00

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

COMPLAINT / INJURY REPORT

1. COMPLAINT NUMBER: CIN-858613546
2. DATE OF COMPLAINT (Month / Day / Year): 3/22/99

3. FORM OF COMPLAINT
a. (1) [X] TELEPHONE (2) [ ] LETTER (3) [ ] VISIT

4. SOURCE OF COMPLAINT
a. (1) [X] CONSUMER (2) [ ] GOVERNMENT (3) [ ] TRADE SOURCE (4) [ ] OTHER
[ ] L [ ] S [ ] F (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include ZIP Code): [redacted]
b. AREA CODE AND TELEPHONE NUMBER
HOME [redacted]
WORK ( )

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT / INJURY
Ms. [redacted] 27 yr. old daughter began using the pdct 2-3 weeks ago. Ea. time she uses it, she develops heart palipitations. The palipitations begin < 1 hr. & last for 1-1½ hrs. Ms. [redacted] also said her daughter is beginning to have mood swings. Ms. [redacted] believes her daughter is taking 3 doses / day as is indicated. See Below

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) [X] NO (2) [ ] YES (If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) [ ] NO (2) [X] YES * *(If "yes" complete items a through d)

a. EIB (HFC - 161) NOTIFIED (1) [X] NO (2) [ ] YES DATE: ____

b. TYPE SYMPTOMS — ONSET (HR.)
(1) [ ] VOMITING
(2) [ ] NAUSEA
(3) [ ] DIARRHEA
(4) [ ] FEVER
(5) [ ] SKIN/EYE IRR.
(6) [ ] HEADACHE
(7) [X] OTHER heart palipitations

c. ATTENDING HEALTH PROFESSIONAL? (1) [X] NO (2) [ ] YES (If "Yes" give name, address and phone number)

d. HOSPITALIZATION REQUIRED? (1) [X] NO (2) [ ] YES (If "Yes" give name, address, phone number and dates)

MAY 1999 RECEIVED DOMESTIC PROGRAMS BRANCH CONSUMER COMPLAINT COORD.

8. PRODUCT AND LABELING
a. BRAND NAME: Metabolife
b. PRODUCT NAME: Metabolife 356
c. SIZE AND PACKAGE TYPE: 90 capl in glass bottle
d. NAME AND LOCATION OF STORE WHERE PURCHASED: [redacted]
e. PACKAGE CODE / SERIAL NUMBER / ETC.: UK
EXP. / USE BY DATE: ____
f. DATE PURCHASED: 3/1/99
g. PRODUCT USED (If "Yes" enter date) (1) [ ] NO (2) [X] YES Date: 3/1/99
h. AMT. REMAINING: UK

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: LOS
b. C.F. NO.: 2027654
c. NAME AND LOCATION OF FIRM (Include ZIP Code): Metabolife Int'l Inc 5070 Santa Fe St San Diego, Ca 92109
d. IMPORT PRODUCT (1) [X] NO (2) [ ] YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEY WORD (1) CODE: R (2) DESCRIPTION: palipitations
b. EVALUATION
(1) [ ] NOT AN FDA OBLIGATION
(2) [ ] OBLIGATION, NO VIOLATION
(3) [X] FDA ACTION INDICATED
(4) [ ] INSUFFICIENT INFORMATION UNABLE TO EVALUATE

b. DISPOSITION
(1) [ ] IMMEDIATE FOLLOW-UP
(2) [ ] F / U NEXT EI
(3) [ ] CLOSED WITHOUT FURTHER INVESTIGATION
(4) [ ] REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) [ ] REFERRED TO STATE / LOCAL AGENCY (Closes File)
(6) [X] REFERRED TO OTHER FDA LOS DISTRICT
(7) [ ] REFERRED TO OCI

11. PRODUCT CODE: 54ECT49

12. INFORMATION COPIES TO:
[ ] HFM-660 [ ] HFZ-343
[ ] HFD-730 [X] HFC-161
[ ] HFV-210 [X] HFS-635
[ ] OTHER ____

13. REMARKS: per the instructions, This is the 1st time her daughter has used this type of pdct. The daughter has seasonal allergies & had a stroke related seizure in the past. Ms. [redacted] will send pamphlet.
Rec'ed 4/24/99

14. NAME AND TITLE OF DISPOSITION OFFICIAL: Ward C Rolle PDM

15. DATE: 4/26/99

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FORM FDA 2516 (1/96)

Adverse Event Questionnaire

Complaint Number: CIN-8586 **Investigator:** D Radke

Consumer Information

Date of Report: 3/22/99 (MM/DD/YY)

Initial Report Source: ☒ORA Consumer Injury
☐Telephone ☐Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Daughter used pcd

Gender: ☒F ☐M Age: 27

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: 0/a 3/1/99
Previous Adverse Effects to Product Type:
☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office):

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
Heart palpitations began 1-1½ hrs after taking. Ms. [redacted] also stated her daughter developed mood swings.

How long did the symptoms last? sporatic event

Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). 3 tablets / day - 1 before a meal

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
None

Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☐No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☒Unknown ☐Not Applicable

Medical Information

Was a health care provider seen?: ☐Yes ☒No
Give health care provider's name, address and telephone number:

Occupation of Health Care Provider: ☐MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results?

What was the medical diagnosis?
What treatment(s) was given (e.g., drugs, other)?

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☐Yes ☐No

[redacted]

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Product Category

1. Adverse event attributed to:
   - ☐ **Medical Food** (under medical supervision) ☐ **Infant Formula**
   - ☒ **Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   - ☐ **Other** (traditional food) _____

Other Product Problems

2. ☐ Foreign Object
(specify): _____

3. ☐ Other (specify):
_____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

Metabolife 356
Weight loss / energy booster.

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐ **Check here if ingredients are unknown**

_____
_____
_____

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

- ☐ Aspartame
- ☐ Monosodium Glutamate
- ☐ Sulfite
- ☐ Other_____
- ☐ Unknown
- ☐ Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☐ Yes ☐ No ☐ Unknown Product Sample Available: ☐ Yes ☐ No ☐ Unknown

Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

Death: ☐ Yes ☒ No

Life-Threatening: ☐ Yes ☒ No

Hospitalization: ☐ Yes ☒ No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: ☐ Yes ☒ No

Did the adverse event result in a congenital anomaly: ☐ Yes ☒ No

[redacted]

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